K100501 1/2

ATRICURE MULTIFUNCTIONAL LINEAR PEN 510(k) SUMMARY

JUN 18 2010

General Information

Date Compiled	February 16, 2010
Classification	Class II (Surgical device, for ablation of cardiac tissue)
Product Code	OCL
Trade Name	AtriCure Multifunctional linear pen
Manufacturer	AtriCure, Inc 6217 Centre Park Drive West Chester, OH 45069
Contact	James L. Lucky VP of Quality Assurance and Regulatory Affairs (513) 755-5754

Indications for Use

The Multifunctional linear pen is a sterile, single use electrosurgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy when connected directly to the AtriCure Ablation and Sensing Unit or to the ASU Source Switch in Ablation mode and the Multifunctional linear pen may be used for temporary cardiac pacing, sensing, recording, and stimulation during the evaluation of cardiac arrhythmias during surgery when connected to a temporary external cardiac pacemaker or recording device.

Predicate Devices

The predicate devices for the AtriCure Multifunctional linear pen are the AtriCure Isolator Transpolar pen (K050459, K061593) and the AtriCure Coolrail linear pen (K073605).

Device Description

The Multifunctional linear pen is a hand-held, sterile, single patient use electrosurgical instrument intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy. When the pen is connected to the AtriCure Ablation and Sensing Unit (ASU) directly or via the AtriCure ASU Source Switch in ablation mode, the device delivers RF energy for cardiac tissue ablation when the operator presses the Footswitch. When the pen is connected to a commercially available temporary pacemaker or recorder the pen is used for temporary cardiac pacing, sensing, recording, or stimulation for the evaluation of cardiac arrhythmias during surgery.

Materials

All materials used in the manufacture of the AtriCure Multifunctional linear pen are suitable for their intended use and have been used in numerous previously cleared products. Testing was conducted in Accordance with ISO 10993-1 to ensure appropriate biocompatibility of all materials.

Testing

Appropriate product testing was conducted to evaluate conformance to product specification and substantial equivalence to predicate devices. In-vitro and in-vivo testing demonstrated that the Multifunction linear pen is able to pace, sense, and stimulate and ablate cardiac tissue as safely and effectively as the AtriCure Isolator Transpolar pen and the AtriCure Coolrail linear pen.

Summary of Substantial Equivalence

The Multifunctional linear pen is equivalent to the predicate products. The indications for use, basic overall function, and materials used are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JUN 18 2010

AtriCure, Inc.
c/o Mr. James Lucky, RAC
Vice President of Quality Assurance and Regulatory Affairs
6217 Centre Park Dr.
West Chester, OH 45069

Re: K100501
Trade/Device Name: AtriCure Multifunctional Linear Pen
Regulation Number: 21 CFR §878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II (two)
Product Code: OCL
Dated: May 20, 2010
Received: May 21, 2010

Dear Mr. Lucky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K100501

Device Name: AtriCure Multifunctional linear pen

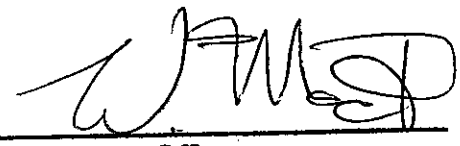
Indications for Use:

- *The Multifunctional Linear Pen is a sterile, single use electrosurgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy when connected directly to the AtriCure Ablation and Sensing unit (ASU) or to the ASU Source Switch in Ablation mode.*
- *The Multifunctional Linear Pen may be used for temporary cardiac pacing, sensing, recording, and stimulation during the evaluation of cardiac arrhythmias during surgery when connected to a temporary external cardiac pacemaker or recording device.*

Prescription Use X (Part 21 CRF 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CRF 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100501